PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Justin M. Crank	Confirmation No.: 2850
Serial No.:	10/647,613	Examiner: J. Hoekstra
Filing Date:	August 25, 2003	Group Art Unit: 3736
Docket No.:	1001.1686101	Customer No.: 28075
For:	ELONGATED INTRA-LUMENAL MEDICAL DEVICE	

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P.O. Box 1450
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 21st of November 2006.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on September 22, 2006. Permission is hereby granted to charge the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $500.00 to Deposit Account No. 50-0413.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at reel 018505, Frame 0868, and an assignment from the inventor, Justin M. Crank, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 014477, Frame 0156.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-32 are pending in the application. Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Samson et al., U.S. Patent No. 5,827,201, in view of Dobson, U.S. Patent No. 5,724,989.

Claims 3, 4, 6, 8, 12, 13, 15, 17, 20, 23, 24, 27, 30 and 31 have been withdrawn from consideration consequent an Examiner-induced requirement for restriction presented in an Office Action mailed November 22, 2005, and thus are not subject to the current appeal.

Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

A Response After Final was filed on August 18, 2006, in which no claim amendments were made, but all pending claims, including updated status identifiers, were presented in a clean version along with accompanying remarks requesting reconsideration in response to a Final Office Action mailed June 21, 2006. An Advisory Action was mailed on September 1, 2006, stating the request for reconsideration was considered, but failed to place the application in condition for allowance.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

The invention relates to medical devices, such as guidewires, catheters, or the like, with portions having improved characteristics. (Specification, page 4, lines 21-30).

Turning now to the claims, claim 1 is an independent claim directed to a medical device (Specification, page 4, lines 21-30; page 5, lines 4-5; reference numeral 100) comprising a coil (reference numeral 110) having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire (reference numeral 305, 400, 500, 600, 700) (Specification, page 7, lines 9-10; page 7, lines 19-22; page 12, lines 10-15; FIGS. 1-7). The wire includes a cross-section (FIGS. 4-7) with a centroid (reference numeral 450, 550, 650, 750; FIGS. 4-7), wherein the wire has a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil greater than a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil (Specification, page 12, line 19 through page 15, line 28).

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1 The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

Claim 2, which depends from claim 1, further recites that the cross-section of the wire is a polygonal shape (Specification, page 7, lines 12-14; FIGS. 3, 4 and 7).

Claim 5, which depends from claim 1, further recites that the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5 (Specification, page 5, lines 26-29).

Claim 7, which depends from claim 1, further recites that the wire is a composite wire (Specification, page 14, line 19; reference numeral 700; FIG. 7) comprising a cross-section (FIG. 7) with a centroid (reference numeral 750; FIG. 7), a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis (Specification, page 14, lines 25-26; FIG. 7). The composite wire includes a first material (reference numeral 710) having a first Young's Modulus at the centroid and a second material (reference numeral 720) having a second Young's Modulus further away from the centroid along the wire radial axis, wherein the second Young's Modulus is greater than the first Young's Modulus (Specification, page 14, line 25 through page 15, line 10; FIG. 7).

Claim 9, which depends from claim 7, further recites that the cross-section of the wire is a polygonal shape (Specification, page 14, lines 21-23; FIG. 7).

Claim 10 is an independent claim directed to a medical guidewire (Specification, page 4, lines 21-30; page 5, lines 4-5; reference numeral 100, FIG. 1) comprising an elongated shaft (reference numeral 130, FIG. 1) including a proximal region having a first outer diameter and a distal region having a second outer diameter that is smaller than the first outer diameter (Specification, page 10, lines 1-10). The medical guidewire further comprises a coil member (reference numeral 110, FIG. 1) connected to the elongated shaft at the distal end of the proximal region and extending from the distal end of the proximal region over at least a portion of the distal region (Specification, page 11, lines 3-13). The coil member has an inner diameter that is

greater than the second outer diameter (Specification, page 1, line 30 through page 2, line 4), wherein the coil member has a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire (reference numeral 305, 400, 500, 600, 700) (Specification, page 7, lines 9-10; page 7, lines 19-22; page 12, lines 10-15; FIGS. 1-7). The wire includes a cross-section (FIGS. 4-7) with a centroid (reference numeral 450, 550, 650, 750; FIGS. 4-7), wherein the wire has a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil greater than a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil (Specification, page 12, line 19 through page 15, line 28).

Claim 11, which depends from claim 10, further recites that the cross-section of the wire is a polygonal shape (Specification, page 7, lines 12-14; FIGS. 3, 4 and 7).

Claim 14, which depends from claim 10, further recites that the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5 (Specification, page 5, lines 26-29).

Claim 16, which depends from claim 10, further recites that the wire is a composite wire (reference numeral 700) comprising a cross-section (FIG. 7) with a centroid (reference numeral 750), a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis (Specification, page 14, lines 25-26; FIG. 7). The composite wire includes a first material (reference numeral 710, FIG. 7) having a first Young's Modulus at the centroid and a second material (reference numeral 720, FIG. 7) having a second Young's Modulus further away from the centroid along the wire radial axis, wherein the second Young's Modulus is greater than the first Young's Modulus (Specification, page 14, line 25 through page 15, line 10; FIG. 7).

Claim 18, which depends from claim 16, further recites that the cross-section of the wire is a polygonal shape (Specification, page 14, lines 21-23; FIG. 7).

Claim 19 is an independent claim directed to a medical device (Specification, page 4, lines 21-30; page 5, lines 4-5; reference numeral 100) comprising a coil (reference numeral 110) having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire (reference numeral 700) (Specification, page 7, lines 9-10; page 7, lines 19-22; page 12, lines 10-15; FIGS. 1-3, 7). The wire includes a cross-section (FIG. 7) with a centroid (reference numeral 750; FIG. 7), a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis (Specification, page 14, lines 25-26; FIG. 7). The composite wire includes a first material (reference numeral 710) having a first Young's Modulus at the centroid and a second material (reference numeral 720) having a second Young's Modulus further away from the centroid along the wire radial axis, wherein the second Young's Modulus is greater than the first Young's Modulus (Specification, page 14, line 25 through page 15, line 10; FIG. 7).

Claim 21, which depends from claim 19, further recites that the cross-section of the wire is a polygonal shape (Specification, page 14, lines 21-23; FIG. 7).

Claim 22, which depends from claim 19, further recites that the cross-section of the wire is a rectangular shape (Specification, page 14, lines 21-23; FIG. 7).

Claim 25, which depends from claim 19, further recites that the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5 (Specification, page 5, lines 26-29).

Claim 26 is an independent claim directed to a medical guidewire (Specification, page 4, lines 21-30; page 5, lines 4-5; reference numeral 100) comprising an elongated shaft (reference numeral 130) including a proximal region having a first outer diameter and a distal region having

a second outer diameter that is smaller than the first outer diameter (Specification, page 10, lines 1-10). The medical guidewire further comprises a coil member (reference numeral 110) connected to the elongated shaft at the distal end of the proximal region and extending from the distal end of the proximal region over the distal region (Specification, page 11, lines 3-13). The coil member has an inner diameter that is greater than the second outer diameter (Specification, page 1, line 30 through page 2, line 4), wherein the coil member has a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire (reference numeral 700) (Specification, page 7, lines 9-10; page 7, lines 19-22; page 12, lines 10-15; FIGS. 1-3, 7). The wire includes a cross-section (FIG. 7) with a centroid (reference numeral 750; FIG. 7), a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis (Specification, page 14, lines 25-26; FIG. 7). The composite wire includes a first material (reference numeral 710) having a first Young's Modulus at the centroid and a second material (reference numeral 720) having a second Young's Modulus further away from the centroid along the wire radial axis, wherein the second Young's Modulus is greater than the first Young's Modulus (Specification, page 14, line 25 through page 15, line 10; FIG. 7).

Claim 28, which depends from claim 26, further recites that the cross-section of the wire is a polygonal shape (Specification, page 14, lines 21-23; FIG. 7).

Claim 29, which depends from claim 26, further recites that the cross-section of the wire is a rectangular shape (Specification, page 14, lines 21-23; FIG. 7).

Claim 32, which depends from claim 26, further recites that the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5 (Specification, page 5, lines 26-29).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 are unpatentable under 35 U.S.C. §103(a) as being unpatentable over Samson et al., U.S. Patent No. 5,827,201, in view of Dobson, U.S. Patent No. 5,724,989.

VII. ARGUMENT

A. *Claims 1, 5, 7, 10, 14 and 16 are patentable over the §103(a) rejection relying on the combination of Samson et al., U.S. Patent No. 5,827,201, and Dobson, U.S. Patent No. 5,724,989.*

The wire forming the coil disclosed in Samson et al. and/or Dobson does not meet the structural limitations of the wire as currently claimed.

Claim 1 recites:

> A medical device comprising:
>
> a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire, the wire comprising:
>
> (a) a cross-section with a centroid;
>
> (b) a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and
>
> (c) a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

Claim 10, which is directed to a medical guidewire, includes similar limitations of a wire forming a coil. The claimed wire forming the coil has a cross-section such that the moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis of the coil.

Appellant notes that the moment of inertia as described in the current application, which is otherwise known as the second moment of area, is a property of a shape which may be used to determine the resistance to bending and deflection of the shape. In general, a shape is more efficient to resist bending when the greater part of its mass is as far as possible from its centroid. This is evidenced by the equations provided at page 13, line 7 of the current application and reproduced below:

$$I_x = \int y^2 \, dA \qquad\qquad I_y = \int x^2 \, dA$$

where I_x is the moment of inertia about the x axis of an object and I_y is the moment of inertia about the y axis of an object.

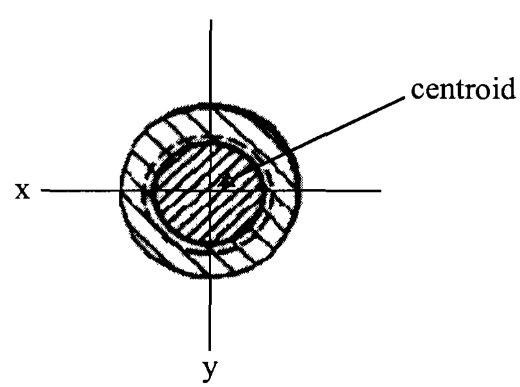
One of skill in the art would conclude that, with a member having a circular cross section, the moment of inertia about the x axis (i.e., I_x) would be equivalent to the moment of inertia about the y axis (i.e., I_y). In order for the calculated moment of inertia about the x axis (i.e., I_x) to exceed the calculated moment of inertia about the y axis (i.e., I_y), a greater amount of mass must be positioned further away from the x axis than the amount of mass positioned away from the y axis.

In formulating the rejection, the Examiner appears to be relying on the teachings of Dobson to teach the claimed wire forming the coil. Appellant disagrees with the Examiner's erroneous statement that a composite coil of two different materials wherein the outer material has a larger Young's modulus than that of the inner material "dictates that the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil." See Final Office Action, June 21, 2006, page 2. The mere indication that an outer material of a member has a larger Young's modulus than that of an inner

material does not, in and of itself, dictate the relationship of the moments of inertia of the member. For instance, occurrences in which all material is concentrically located about the centroid, such as is the case with the spring 14 of Dobson as discussed below, would result in equal moments of inertia about all planes passing through the centroid. It follows that the Examiner's assertion that a composite coil of two different materials wherein the outer material has a larger Young's modulus than that of the inner material "<u>dictates</u> that the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil" (emphasis added) is clearly not a true statement in all instances, including the instance disclosed in Dobson.

Contrary to the Examiner's assertion, the multi-layer wire of the spring 14 taught in Dobson fails to exhibit the claim limitations that the wire forming the coil has a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil which is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

The cross-section of the wire of the spring 14 disclosed in Dobson is reproduced below with the inclusion of a longitudinal axis of the spring (axis x) running through the centroid and a radial axis of the spring (axis y) running through the centroid.



In order to illustrate the orientation of the x axis of the above figure as being parallel to the longitudinal axis of the spring 14, and the y axis of the above figure as being parallel to the radial axis of the spring 14, FIGS. 2 and 3 of Dobson, are reproduced in their entirety below.

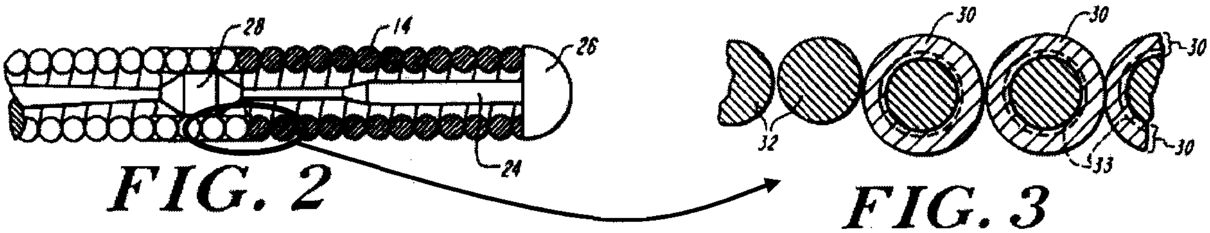


FIG. 2 FIG. 3

The portion of the spring 14 encircled in FIG. 2 is representative to the portion of the spring 14 illustrated in more detail in FIG. 3, showing cross-sections of adjacent turns of the wire forming the spring 14. Concerning that illustrated in FIGS. 2 and 3, Dobson states:

> According to the present invention, the wire forming the coils in the distal approximately 2.5 cm. (about 1 inch) of spring 14 includes a annular, circumferentially surrounding layer 30 of radiopaque material having an outer diameter not more than about 0.002 in. (about 0.05 mm.) greater than that of the stainless steel central portion 32 of spring 14 on which the radiopaque material is deposited. In FIG. 2, the spring coils which include layer 30 are cross-hatched; FIG. 3, which is greatly enlarged, shows both annular layer 30 and the central portion 32 of the stainless steel wire that the layer 30 circumferentially surrounds.

Dobson, at column 3, lines 26-36. Thus, axis x included in the illustrative figure reproduced above is indeed an axis running through the centroid of the cross-section of the wire and parallel to the longitudinal axis of the spring 14 (i.e., along the guidewire's length); and the axis y included in the illustrative figure reproduced above is indeed an axis running through the centroid of the cross-section of the wire and parallel to the radial axis of the spring 14.

The dimensional characteristics and material distribution of the cross-section of the wire of the spring 14 illustrated above as derived from FIG. 3 of Dobson, which is bi-axially symmetrical (e.g., symmetrical about the x and y axes), would yield a moment of inertia with

respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis of the spring 14 equal to a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis of the spring 14. Namely, as the cross-section of the inner material 32 of the wire is circular in nature and the outer material 30 of the wire is concentrically placed around the inner material 32, an equal amount of material would be located at all radial locations from the center of the cross-section (which also would be the centroid in this case). Using the equations which are provided at line 7 of page 13 of the present application, one of skill in the art would conclude that the moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis (axis x) of the spring 14 would be equal to the moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis (axis y) of the spring 14. Thus, Dobson does not exhibit the claim limitations that the wire forming the coil has a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil which is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

One of ordinary skill in the art would conclude that the ratio of the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of a member to the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of a member would be 1:1 in a member having a bi-axially symmetrical cross-section such as the circular cross-section disclosed in Dobson. This is also evidenced by the equations provided at line 7 of page 13 of the current application. In order to change the ratio, more material would need to be moved away from the x-axis (longitudinal axis) without moving the same or greater amount of material away from the y-axis (radial axis), or vise versa.

For instance, FIGS. 4-7 of the current application, which are reproduced below, illustrate cross-sections in which the moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis of the coil (x axis) is greater than the moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis of the coil (y axis).

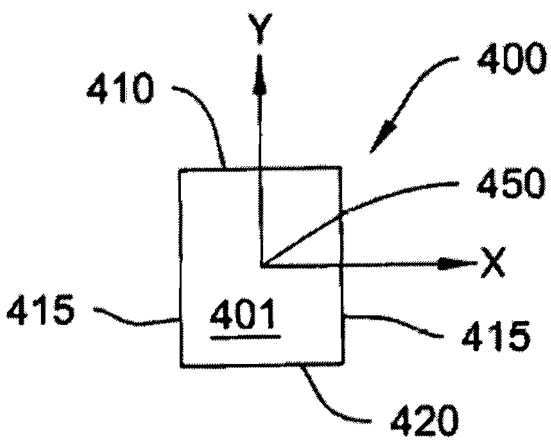


Fig.4

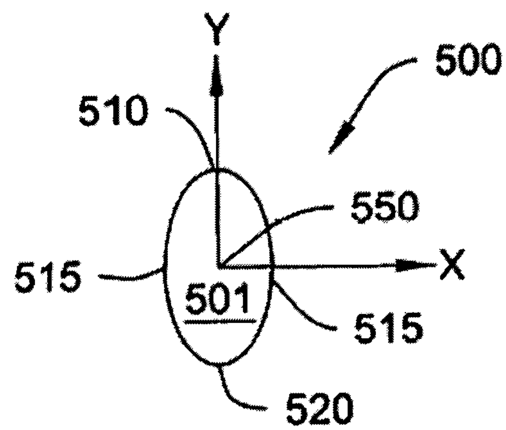


Fig.5

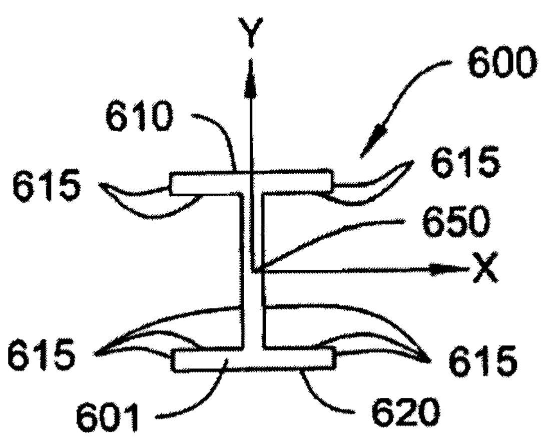


Fig.6

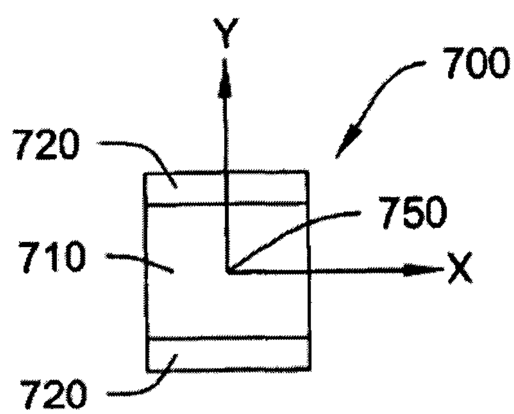


Fig.7

In each of FIGS. 4-7 more material is located further away from the x-axis than material located away from the y-axis. One of skill in the art, utilizing the equations provided at line 7 of

page 13 of the current application, would conclude that the cross-sections illustrated in FIGS. 4-7 would have a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis of the member which is greater than a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis of the member.

In carefully reviewing the teachings of Dobson as well as the teachings of Samson et al., the cited references only disclose the use of a coil formed of a wire having a circular cross-section. As discussed above, a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis of the member which is greater than a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis of the member is not generally characteristic of a wire having a circular cross-section. Thus, neither Samson et al. nor Dobson disclose a wire that has a cross-section having a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the longitudinal axis of the coil which is greater than a moment of inertia with respect to an axis running through the centroid of the cross-section and parallel to the radial axis of the coil.

B. *Claims 19, 25, 26 and 32 are patentable over the §103(a) rejection relying on the combination of Samson et al., U.S. Patent No. 5,827,201, and Dobson, U.S. Patent No. 5,724,989.*

The Examiner's basis of rejection is not supported by the teachings of Samson et al. and/or Dobson.

Claims 19 recites:

> A medical device comprising:
> a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire, the composite wire comprising:

(a) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(b) a first material having a first Young's Modulus at the centroid; and

(c) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

Claim 26, which is directed to a medical guidewire, includes similar limitations of a composite wire forming a coil.

Concluding that Samson et al. fail to teach a composite wire as claimed in claims 19 and 26, the Examiner turns to the teachings of Dobson in formulating the rejection of claims 19 and 26. Dobson teaches a spring 14 composed of two different materials 30, 32. Dobson suggests the spring 14 is preferably formed of a stainless steel core material and a layer of gold deposited on the stainless steel core. See Dobson, Abstract; column 1, line 67-column 2, line 2. The Young's modulus of stainless steel typically ranges between 195-210 GPa and the Young's modulus of gold is about 78 GPa. However, in formulating the rejection of claims 19 and 26, the Examiner gives values of the Young's modulus of tungsten carbide and Nitinol, stating that the Young's modulus of tungsten carbide ranges between 450-650 GPa and the Young's modulus of Nitinol ranges between 28-75 GPa. See Final Office Action, June 21, 2006, at page 3. Appellant respectfully asserts these values indicated by the Examiner in formulating the rejection are irrelevant to the spring 14 taught in Dobson. Thus, the asserted rejection of these claims is unsupported by the express teachings of Samson et al. and Dobson.

C. *Claims 2, 9, 11, 18, 21, 22, 28 and 29 are patentable over the §103(a) rejection relying on the combination of Samson et al., U.S. Patent No. 5,827,201, and Dobson, U.S. Patent No. 5,724,989.*

Neither Samson et al. nor Dobson teaches a wire forming a coil that has a polygonal or rectangular cross-section.

In formulating the rejection of underlying claims 1, 10, 19 and 26, the Examiner has equated the coil 148, 188 taught by Samson et al. with the claimed coil. See Final Office Action, June 21, 2006, at page 2. Claims 2, 9, 11, 18, 21, 22, 28 and 29 each further define the cross-section of the wire forming the coil as claimed as being polygonal or rectangular. The Examiner states with reference to lines 54-58 of column 9 that "Samson et al discloses a wire of polygonal and rectangular cross section." Final Office Action, June 21, 2006, page 3. Appellant respectfully disagrees with the Examiner's suggestion that this passage teaches that which is claimed in claims 2, 9, 11, 18, 21, 22, 28 and 29.

The cited passage of Samson et al. is not describing either the coil 148 or the coil 188 which the Examiner has equated with the claimed coil in formulating the rejection. Instead, the cited passage of Samson et al. is directed to metallic ribbons forming the braid (146, 178), an entirely different component of the device taught by Samson et al. As shown in FIGS. 4 and 6A/B, the disclosed coil is denoted by reference numbers 148 and 188 respectively, whereas the disclosed braid is denoted by reference numbers 146 and 178 respectively.

It should be noted that the guidewire taught by Samson et al. generally includes four components; a core wire, a ribbon braid, a coil, and a polymeric layer placed over the assembly of metallic components. See Samson et al., column 4, lines 8-21. Indeed, the written disclosure of Samson et al. is divided into appropriately titled subsections describing the various

components. The passage cited by the Examiner in formulating the rejection is not included in a subsection committed to coils, but rather is included in the portion of Samson et al. subtitled "Braids". See Samson et al., column 8, line 61. Samson et al. expressly describe that the braids are constructed of ribbons. See Samson et al., column 9, line 30 through column 10, line 19. It is these ribbons, which form the braid, that are described in detail at lines 54-58 of column 9. This disclosure of the braid construction is consistent with the braids 146/178 illustrated in FIGS. 4 and 6A/B.

As shown in FIGS. 4 and 6A/B, the coil 148, 188, which the Examiner equates to the claimed coil in rejecting claims 1, 10, 19 and 26, has a circular cross-section. In carefully reviewing the teachings of Samson et al., Samson et al., as well as Dobson, only disclose the use of a coil having a circular cross-section. Thus, neither Samson et al. nor Dobson disclose a coil that has a polygonal or rectangular cross-section.

D. Conclusion.

For the reasons stated above, the rejection of claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 under 35 U.S.C. §§103(a) should be reversed.

Respectfully submitted,

Justin M. Crank

By his attorney,

David M Crompton

Date: 11/21/06

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VIII. CLAIMS APPENDIX

1. A medical device comprising:

a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire, the wire comprising:

(a) a cross-section with a centroid;

(b) a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and

(c) a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

2. The medical device according to claim 1, wherein the wire cross-section is a polygonal shape.

5. The medical device according to claim 1, wherein the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5.

7. The medical device according to claim 1, wherein the wire is a composite wire comprising:

(a) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(b) a first material having a first Young's Modulus at the centroid; and

(c) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

9. The medical device according to claim 7, wherein the wire cross-section is a polygonal shape.

10. A medical guidewire comprising:

(a) an elongated shaft including a proximal region having a first outer diameter and a distal region having a second outer diameter that is smaller than the first outer diameter;

(b) a coil member connected to the elongated shaft at the distal end of the proximal region and extending from the distal end of the proximal region over at least a portion of the distal region, the coil member having an inner diameter that is greater than the second outer diameter, wherein the coil has a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a wire, the wire comprising:

(i) a cross-section with a centroid;

(ii) a moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and

(iii) a moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein the moment of inertia

with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil.

11. The medical guidewire according to claim 10, wherein the wire cross-section is a polygonal shape.

14. The medical guidewire according to claim 10, wherein the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5.

16. The medical guidewire according to claim 10, wherein the wire is a composite wire comprising:

(a) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(b) a first material having a first Young's Modulus at the centroid; and

(c) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

18. The medical device according to claim 16, wherein the wire cross-section is a polygonal shape.

19. A medical device comprising:

a coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire, the composite wire comprising:

(a) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(b) a first material having a first Young's Modulus at the centroid; and

(c) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

21. The medical device according to claim 19, wherein the wire cross-section is a polygonal shape.

22. The medical device according to claim 19, wherein the wire cross-section is a rectangular shape.

25. The medical device according to claim 19, wherein the wire is formed of a material with a Poisson's ratio from 0.25 to 0.5.

26. A medical guidewire comprising:

(a) an elongated shaft including a proximal region having a first outer diameter and a distal region having a second outer diameter that is smaller than the first outer diameter;

(b) a coil member connected to the elongated shaft at the distal end of the proximal region and extending from the distal end of the proximal region over the distal region, the coil member having an inner diameter that is greater than the second outer diameter, wherein the coil having a longitudinal axis and a radial axis orthogonal to the longitudinal axis, formed from a composite wire, the composite wire comprising:

(i) a cross-section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis and a wire radial axis parallel to the coil radial axis;

(ii) a first material having a first Young's Modulus at the centroid; and

(iii) a second material having a second Young's Modulus further away from the centroid along the wire radial axis; wherein the second Young's Modulus is greater than the first Young's Modulus.

28. The medical guidewire according to claim 26, wherein the wire cross-section is a polygonal shape.

29. The medical guidewire according to claim 26, wherein the wire cross-section is a rectangular shape.

32. The medical guidewire according to claim 26, wherein the wire is formed of a material with a Poisson's ratio from 0.3 to 0.5.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.